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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

application of )  
Gary D. HODGEN et al.1 ) Group Art Unit: 1205  
Serial No.: 08/462,703 ) Examiner: K. Jordan  
Filed: June 5, 1995 )  
For: ANTIPROGESTIN METHOD AND KIT FOR REDUCING SIDE EFFECTS  
ASSOCIATED WITH LOW DOSAGE HRT, ORAL CONTRACEPTION AND  
REGULATING MENSES

INFORMATION DISCLOSURE STATEMENT

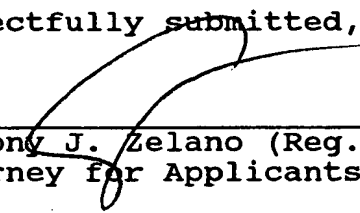
Assistant Commissioner for Patents  
Washington, D. C. 20231

SIR:

Attached are references which were of record during the prosecution of U. S. Patent No. 5,468,736, a copy of which is being filed. Also being filed are copies of the responses from the prosecution of '736 in which the references were discussed, i.e., the responses of July 22, 1994, and March 6, 1995.

Gary D. Hodgen, one of the named inventors for the above-identified application is also a named inventor on '736.

Respectfully submitted,

  
Anthony J. Zelano (Reg. No. 27,969)  
Attorney for Applicants

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.  
Arlington Courthouse Plaza I  
2200 Clarendon Boulevard, Suite 1400  
Arlington, Virginia 22201  
(703)812-5311

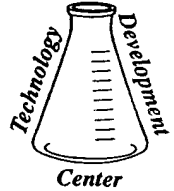
Filed: May 8, 1996

[SCH 1309 C3]



## Gary D. Hodgen, Ph.D.

Professor, Department of Obstetrics and Gynecology  
Chair, The Howard and Georgeanna Jones Institute for Reproductive Medicine  
President, The Jones Institute Foundation  
601 Colley Avenue, Norfolk, Virginia 23507-1627  
Telephone (757) 446-5266 • Facsimile (757) 446-5905



October 17, 1997

**VIA HAND DELIVERY**

Examiner Kimberly Jordan  
Group Art Unit 1205  
United States Patent and Trademark Office  
Washington DC 20231

Re: Patent Application Ser. Nos. 08/462,703 and 08/462,705

Dear Examiner Jordan:

I am one of the inventors in each of the two patent applications noted above. Since the applications are being prosecuted by the Assignee, I have not been involved but would like you to be aware of some brief comments. As you will see, I have sent a copy of this letter to the attorneys prosecuting the applications.

Both of these applications (08/462,703 and 08/462,705) are continuations of an application bearing Serial No. 08/115,008 which was filed on September 1, 1993. You had allowed the parent '008 application (Notice of Allowance dated February 5, 1996), but the Assignee permitted it to go abandoned and to be replaced with these two applications (08/462,703 and 08/462,705).

As a result of various amendments, the claims in applications 08/462,703 and 08/462,705 are presently identical. It is my understanding that is not permitted.

More importantly, what I would like to bring to your attention is the fact that there are claims pending in these two applications which are generic to, or specific to, continuous antiprogesterin administration. However, the invention which is the subject of these applications is, and always has been, a method in which the antiprogesterin is administered intermittently. We did not disclose in this application, intentionally, any protocol in which antiprogesterin administration was continuous. These generic or specific "continuous" claims were added by amendment without any basis in the applications.

In particular, I call your attention to the summary of the invention on page 4 of the text which indicates that the invention relates to avoiding bleeding problems by a method "which comprises periodically inducing menses by administering...an anti-progesterin...." In the next paragraph, it is pointed out that the pharmaceutical composition contains antiprogesterin "arranged to be ingested after ingestion for at least 20...consecutive days of at least 20...unit doses containing amounts of an estrogen and/or progesterin..."

Examiner Jordan,  
October 17, 1997  
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Gary D. Hodgen, PhD

The importance of intermittent administration is emphasized throughout the application. Intermittent administration is the invention.

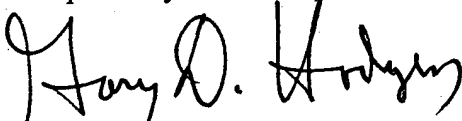
I already have patents relating to protocols which involve continuous antiprogesterin administration. That is separate and distinct from intermittent administration. The inventive concepts involved are totally different.

The inventions relating to continuous antiprogesterin administration were not invented by me and Kristoff Chwalisz as co-inventors. We are co-inventors only to the extent of an intermittent antiprogesterin protocol when used in combination with an estrogen and a progestin together.

Kristoff Chwalisz and I are the co-applicants in both applications 08/462,703 and 08/462,705. Both applications describe only intermittent antiprogesterin protocols. The claims in the applications should be limited to the intermittent antiprogesterin administration exclusively when used in combination with an estrogen and a progestin together.

When the claims in these applications are appropriately limited to the intermittent antiprogesterin protocols described above, I agree with your previous determination that the inventions are patentable.

Respectfully submitted,



Gary D. Hodgen, PhD

GDH/srb

cc: Anthony J. Zelano, Esq.  
Edward A. Meilman, Esq.  
David E. Thiel, CPA  
Shelly R. Barger